

Additional Information for Pending PRIA Label Amendment

January 31, 2011

Mr. John Hebert, Product Manager 7
Document Processing Desk - **AMEND**
Office of Pesticide Programs – **7504P**
U.S. Environmental Protection Agency
One Potomac Yard, South Building, Room S-4900
2777 South Crystal Drive
Arlington, VA 22202

Dear Mr. Hebert:

Subject: Scimetrics Ltd. Corporation
Kaput® Field Rodent Bait B, EPA Reg. No. 72500-11
OPPT Decision Number: D-394038
EPA Diphacinone Risk Assessment April 19, 2009
Steven Bradbury Letter to Polly Cross, Wyoming Dept. of Agriculture. December 21, 2010

Scimetrics Ltd. Corporation is submitting the enclosed documents in continuing support of a label amendment to add prairie dogs to subject product's label and in response to the Agency's April 19, 2009 "Ecological Risk Assessment Evaluating Expanded Uses for the diphacinone (0.0025%) component of Kaput® Field Rodent Bait" for use on Black Tailed Prairie Dogs".

Volume 1 of 9: Administrative Documents:

1. Application for Pesticide: Amendment
2. Five copies of revised labeling
3. Certification with Respect to Citation of Data
4. Data Matrix (Agency Internal Use Copy)
5. Data Matrix (Public File Copy)

Volume 2 of 9: Product Performance Data: Assigned MRID Number: 48373001

Polyakova, L. (2010): Kaput-D COMBO BAIT (EPA Reg. No. 72500-11): Determination of Field Stability. Unpublished research report prepared by Genesis Laboratories, Inc., Wellington, CO. 37 pp. Guideline Number 830-6317 (modified). (3 copies)

Volume 3 of 9: Product Performance Data: Assigned MRID Number: 48373002

Ingenloff, K. and Soniat, M. (2010): Exposure of Kaput® Field Rodent Bait B to Northern Bobwhite Quail (*Colinus virginianus*). Unpublished research report prepared by Genesis Laboratories, Inc., Wellington, CO. 44p. Guideline Number 71-5. (3 copies)

Volume 4 of 9: Product Performance Data: Assigned MRID Number: 48373003

Baroch, J.A. (1996): Public Literature Citations: Field Efficacy of Diphacinone Grain Baits Used to Control the California Ground Squirrel. For Proceedings of the 17th Vertebrate Pest Control Conference. 10p.

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Volume 5 of 9: Product Performance Data: Assigned MRID Number: 48373004
Wikipedia. 2011. Public literature Citation: Mallard and Bobwhite Quail 13p. (3 copies)

Volume 6 of 9: Product Performance Data: Assigned MRID Number: 48373005
Poché, D. (2010): Exposure of Kaput® Field Rodent Bait B to Mallard Ducks (*Anas platyrhynchos*). Unpublished research report prepared by Genesis Laboratories, Inc., Wellington, CO. 47p. Guideline Number 71-5. (3 copies)

Volume 7 of 9: Product Performance Data: Assigned MRID Number: 48373006
Exposure of Rozol Prairie Dog Bait to northern bobwhite quail EPA Reg. No. 7173-286. Unpublished research report prepared by Genesis Laboratories, Inc., Wellington, CO. 36 pp. Guideline 71-5. (3 copies)

Volume 8 of 9: Product Performance Data: Assigned MRID Number: Reject (07)
Poché, R. (1988): Public Literature Citation: Rodent Tissue Residue and Secondary Hazard Studies with Bromadiolone. Bulletin OEPP/EPPO Bulletin 18. 12p. (3 copies)

Volume 9 of 9: Product Performance Data: Assigned MRID Number: 48373008
Poché, D. (2008): Secondary Toxicity Study with American Alligators (*Alligator mississippiensis*) Fed Warfarin Killed Norway Rats (*Rattus norvegicus*). Unpublished research report prepared by Genesis Laboratories, Inc., Wellington, CO. 26p. Guideline Number 71-5. (3 copies)

After review of the referenced "Ecological Risk Assessment", we are submitting the enclosed studies to address the data gaps outlined in the risk assessment. In addition, we have added a previously submitted study to the data matrix (MRID Number 481908-01) to support the pending PRIA action.

In addition, information addressed in this document applies to comments referenced in a letter to the Wyoming Department of Agriculture letter by Dr. Steven Bradbury on December 21, 2010. Comments made by government wildlife agencies and environmental groups are generalities and do not reflect recent data on studies conducted on birds and other wildlife using diphacinone and other anticoagulants.

Since the California ground squirrel is located in five states (AZ, CA, NV, OR and WA) and Black-tailed prairie dogs are located in eleven (11) states (AZ, CO, KS, NE, ND, NM, MT, OK, SD, TX, and WY), limiting the use of this product to only those states in which each species is found would help lessen potential exposure to non-target wildlife. The enclosed label has been revised to reflect this limitation.

In addition, we agree with the Agency's request to add the statement "Use of this product may pose a hazard to endangered species. Do not use this product within prairie dog towns where the black-footed ferret has been released and without first contacting endangered species specialists at a U.S. Fish and Wildlife Service office." to the "Endangered Species Consideration" statements on the label. The addition of this language will help lessen potential exposure to the black footed ferret whose primary food source is the black-tailed prairie dogs. The enclosed label has been revised to add this language.

Here are more specific comments. Reference: Ecological Risk Assessment Evaluating Expanded Uses for the diphacinone (0.0025%) component of Kaput Field Rodent Bait B for use on Black Tailed Prairie Dogs. Author: Ron Dean, USEPA. April 19, 2009. This risk assessment was received by Scimetrix Ltd. Corp. in June 2010. In a meeting with the EPA, Rodenticide group, on August 18, 2010, Section 1.0 Executive Summary, part 1.2 Potential risks to non-target organisms, the points highlighted in the EPA document were discussed. Information is provided in

this summary document to address the issues of concern by the Agency, and to request a reassessment of diphacinone at a lower level of 0.0025%. The comments follow the numbered items in the EPA Risk Assessment.

- 1) This section assumes misuse by the applicator. The application is required to be made 6" below the ground surface. According to the Merriam-Webster Dictionary Thesaurus, below ground is defined as "under the level of the ground". Used correctly by Certified Applicators, there is little potential for unintended exposure of diphacinone. That is part of the definition of RUP products; it has to be applied by a trained, licensed applicator, or someone directly under his supervision. The half-life of diphacinone in light is a matter of days, when formulated on grain. Most of the bait placed into the burrow will be consumed by the prairie dog with 1-3 days. A recent study by Polyakova (Volume 2) showed that 61% of the diphacinone in a grain formulation (EPA Reg. 72500-11) placed on the ground surface degraded within 14 days. Spacing the applications by weeks ensures residues in the tissues of the prairie dog will be low by the time the rodent expires. A study by Fisher et al 2003 (MRID Number 481908-01), demonstrated the half-life of diphacinone in rodent tissues was **three days**. Bait on the surface would be consumed by the species and the half-life of diphacinone in sunlight is relatively short. Scavengers and predators feeding on prairie dogs would ingest relatively low residues of diphacinone. Bird exposure studies with diphacinone presented in this submission reflect a worse-case scenario and don't take into account degradation of diphacinone.
- 2) Any bait that may be inadvertently moved to the surface would be exposed to other prairie dogs and consumed. Birds that feed on the bait would not be affected by the low level of diphacinone, rapid elimination and tolerance to the compound. Volume 3 is a recent study with diphacinone on bobwhite quail by Ingenloff and Soniat (2010) in a confined pen study where birds were exposed for 14 days to a choice of the grain bait (EPA Reg. No. 72500-11) and commercial quail feed. In this worse-case experimental design, about 40% of the total feed consumption was the Kaput-D Field Rodent B. After the 14-day exposure, birds were presented the commercial diet and observed for another 14 days. At completion of the study, all birds were necropsied and none showed signs of anticoagulant poisoning during or after the exposure period. None of the birds died or showed effects to the diphacinone ingestion.
- 3) Treated prairie dogs are confined to their home range and do not move off the treated site. In applying bait, farmers generally treat the entire prairie dog town, which has borders and burrows within the town. Predators or scavengers may find a prairie dog carcass that has died above ground. Because of the lower concentration of the bait and the relatively short half-life of diphacinone in tissues, the potential of such an exposure posing a problem would be extremely low. In a study conducted by the USDA National Wildlife Research Laboratory (G. Whitmer, Personal Communications) using chlorophacinone, treated bait was presented to prairie dogs. The assessment by biologists is that the residues are low and would not create a problem for either carnivores or birds. After extensive field use of the subject bait in Colorado, Wyoming, Texas, Nebraska, and Kansas (via an EPA approved SLN), there were no reports of non-target wildlife issues, even after extensive surveillance by the Colorado State Department of Agriculture. No negative reports were from any of the states where the diphacinone was used for two years.
- 4) The assumption may be correct, but the residues of diphacinone would be very low. In a study done by Baroch (Volume 4) on California ground squirrels, carcasses collected from the study site were analyzed for diphacinone residues. The mean total diphacinone in the entire carcass of squirrels collected from plots baited with 0.005% and 0.01% diphacinone bait was 0.48 and 0.46 mg, respectively. These data are from a mammal that has a relatively shallow burrow system compared to a prairie dog. To ensure an even lower

potential for excess residues, Scimetrics developed a product with ½ and ¼ the amount of diphacinone baits as used by the State of California and that are approved for above ground use by the USEPA. The study by Ingenloff and Soniat, cited above, showed that bobwhite quail ate an average of 5,200 mg of diphacinone-treated bait daily for 14 days and displayed no signs of anticoagulant poisoning. This was an extreme exposure scenario and would never be observed in the wild, since prairie dog towns are not preferred bobwhite quail habitat.

Risks to terrestrial animals: Diphacinone residues will not be present in body tissues of target and non-target primary consumers for weeks, as proven in the Fisher et al study cited above. The effects on reptiles for a second generation anticoagulant were documented by Poché (Volume 8). Prairie rattle snakes were fed bromadiolone-killed mice over a 30-day period and showed no effects of anticoagulant poisoning. Anticoagulants do not affect reptiles the same way they impact mammals.

Risks to aquatic animals: Prairie dog towns are on higher ground generally away from streams and ponds. The formulated bait contains a binder, which adheres the active ingredient to the grain. After bait application, if there is rainfall, the diphacinone will not wash off the bait and drain into watersheds. In addition, diphacinone is virtually insoluble in water. Furthermore, a study conducted by Poché (Volume 9) with American alligators showed no adverse effects in the reptile. After feeding Norway rats 0.025% warfarin bait until the rodents died, rats were fed to alligators for 30 days. Anticoagulants do not affect reptiles the same way they impact mammals.

Risks to listed species: In the label, ENDANGERED SPECIES CONSIDERATIONS, the following is required labeling "Do not use this product within prairie dog towns where the black-footed ferret has been released without first contacting endangered species specialists, U.S. Fish & Wildlife Service". Using this bait within those areas is A VIOLATION OF FEDERAL LAW.

1.3 Key uncertainties and data gaps: Prairie dog bait is approved for use between October 1 and March 15 the following year, or before spring green-up of prairie grasses [vegetation], whichever occurs later. The need for reproductive studies is not justified and waivers would, therefore, be requested. The baiting period is basically the non-breeding season for most birds.

Mallards: The mallard inhabits mostly wetlands, including parks, small ponds and rivers, and usually feeds by dabbling for plant food or grazing (Volume 5). Mallards don't eat grain or products containing grain, as shown in the results of a pen study exposing mallards to 0.0025% diphacinone bait (Volume 6). Sacrificing mallards for a reproduction study would be cruel and a waste of birds, and serve no purpose. Waterfowl are not at risk because of the use of Kaput Field Rodent Bait B. Any requirement for an avian reproduction study is not applicable for mallards since they do not consume the bait, nor do they inhabit prairie dog towns.

Bobwhite quail: The bobwhite quail study cited earlier (Volume 3) showed no diphacinone acute effects. As with mallards, a prairie dog town does not serve as habitat to support bobwhite quail, the upland game species model for avian reproduction. The same study design using Chlorophacinone (Rozol) resulted in 5% of the bobwhite quail being killed by the bait (Volume 7). These data contradict the assessment made by the US Fish & Wildlife Service in a letter to the EPA dated December 7, 2007 to the EPA, as reference in a letter from Steven Bradbury to the Wyoming Department of Agriculture, dated December 21, 2010. In addition, Volume 5, documents the fact that quail reproduction typically begins in mid-April, which is toward the end of the prairie dog baiting season. Diphacinone does not bioaccumulate, nor would bait be available continuously to any bird for 20 weeks, as required in a reproduction study. Should bobwhite quail be forced onto a prairie dog town, there is insufficient escape cover for quail they would vacate the site. This would be a misuse of animals for laboratory research, since bobwhite quail and mallards are not at risk in terms of reproductive effects. The proposed label limits the use of the product for control of Black-tailed prairie dogs between October 1 and March 15 of the following year, or before spring green-up of prairie

grasses [vegetation], whichever occurs later (in Colorado between November 1 and March 15); it is not a year-round baiting system. The purpose of an avian reproduction study is to assess the prolonged exposure to a pesticide. Using the Bobwhite quail as the upland game species representative for avian reproduction and according to Wikipedia (Volume 5), the Bobwhite quail breeding season typically begins in mid-April and the non-breeding season is roughly October to April. The use of this product for control of Black-tailed prairie dogs does **not** coincide with the Bobwhite or Mallard breeding seasons, but with the non-breeding season. Any overlap with the quail breeding season occurs at the end of the prairie dog baiting season and early breeding season for the quail or mallards.

The effects of diphacinone on terrestrial or aquatic plants do not pose an issue, since diphacinone is virtually insoluble in water. Plant uptake would be highly improbable, nor is the compound phytotoxic.

2.0 Problem Formulation

2.2.1 Nature of the chemical stressor

Bioconcentration. As demonstrated in the Fisher et al study cited previously, diphacinone has a half-life in tissues of 3 days and does not bioaccumulate; it breaks down relatively quickly in the pure form under UV light, and sunlight (Volume 2). Diphacinone in formulated bait, if moved out of the burrow by an animal, would degrade fairly rapidly, based on the approximate use rate of 10 lbs per acre (113.5 mg diphacinone), or 0.003 mg/ft².

According to Fisher et al (MRID No. 481908-01) the persistence of sublethal oral doses of diphacinone in the livers of laboratory rats was 3 days, not weeks. Fisher et al suggest that diphacinone would persist for a shorter time period in the environment, and therefore, would be a reduced risk of secondary poisoning to predators and scavengers. These data differ from the suppositions made by the US Fish & Wildlife Service, in the letter to the EPA referenced above.

Conceptual Model. Based on the information presented herein, Scimetrics requests that EFED do a reassessment of diphacinone for this product. The major components as far as exposure and effects in non-target species, such as BIOACCUMULATION AND FOOD CHAIN MAGNIFICATION, REDUCED REPRODUCTION AND SURVIVAL OF AQUATIC ORGANISMS AND REDUCED REPRODUCTION AND SURVIVAL OF TERRESTRIAL NON-TARGET ORGANISMS, are all affected by consideration of the data presented.

Based on the information presented herein, we request that EFED conduct a reassessment of diphacinone for this product in support of the request to add use on prairie dogs.

When reviewing the revised label, please note the expiration date deletion. This is supported by the current approved CSF and our storage stability data (MRID 469665-03)

Please contact me at 970-482-1330 or sue@scimetricsltd.com if you have any questions or require additional information.

Sincerely,



Sue Valentine
Regulatory Manager